UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO.: 05-10403DPW

LLOYD F. AUDETTE,
Plaintiff,

V.

UMASS CORRECTIONAL HEALTH,
A Commonwealth Medicine Program,
Defendant, and

DEPARTMENT OF CORRECTON
Kathleen M. Denney, Commissioner,
Defendant.

STATUS REPORT

NOW COMES the medical defendant, *UMASS Correctional Health*, (hereinafter the "defendant"), and hereby submits this Status Report pursuant to Judge Woodlock's Procedural Order dated May 9, 2005.

A. BACKGROUND

On or about February 24, 2005, plaintiff, Lloyd Audette, a pro se prisoner incarcerated in the Souza-Baranowski Correctional Center ("SBCC"), filed a Complaint with the United States District Court for the District of Massachusetts, alleging violations of his statutory and civil rights (American with Disabilities Act and the 8th Amendment) against UMASS Correctional Health ("UMCH"). Specifically, the plaintiff alleges that UMCH deliberately denied him treatment for his HIV, Hepatitis C, weight loss, and ankle injury, and that UMCH discriminated against him based on these medical conditions.

B. PENDING MOTIONS

On March 7, 2005, this Court denied plaintiff's February 24, 2005, Motion for a Temporary Retraining Order ("TRO"). However, Mr. Audette renewed his Motion for a TRO on May 2, 2005, while also filing a Motion to Amend the Complaint and the Pleadings. (See Exhibit 1 attached, District Court Docket). As such, the following motions are currently pending before this Court:

1.) Plaintiff's May 2, 2005 Motions to Amend the Complaint and the Pleadings to include additional parties.

Mr. Audette seeks to include Charlie Black, UMCH Health Services Administrator for the SBCC, and Dr. Lorraine Hazard, M.D., a UMCH doctor employed at the SBCC. While the defendant does not oppose this Motion, UMCH continues to deny the allegations set forth in plaintiff's Complaint and TRO.

2.) Plaintiff's May 2, 2005 Renewed Motion for a TRO.

Mr. Audette filed a Renewed Motion for a TRO on May 2, 2005, on the grounds that the defendant is still indifferent to his serious medical needs, by not appropriately treating his HIV, his weight loss, or by providing him footwear. Mr. Audette also alleges that Charlie Black lied in defendant's March 2005 Opposition to plaintiff's TRO. (See Exhibit 2 attached, Plaintiff's Renewed Motion for a Restraining Order.

Pending the outcome of the upcoming Status Conference, the defendant intends to file a formal opposition to plaintiff's Renewed Motion for a TRO. As explained more fully below, there is no merit to Plaintiff's Motion for TRO, and no evidence to support a claim of deliberate indifference. Mr. Audette's medical condition is being closely monitored by the physicians at SBCC, with close consultation by a team of infectious disease and endocrinology specialists familiar with his medical condition. For the reasons set forth below, the defendant opposes plaintiff's renewed Motion for a TRO.

C. MR. AUDETTE'S MEDICAL STATUS

In response to the Court's inquiry, defense counsel recently met with Mr. Audette's treating physicians at SBCC (Dr. Lorraine Hazard, and Dr. Phillip Tavares). In addition, defense counsel also spoke via telephone with his infectious disease nurse and one of the infectious disease specialists following his care, Dr. David Stone. Dr. Stone is Board Certified in infectious disease and practices at both Lemuel Shattuck Hospital and Tufts-New England Medical Center. He is not at UMass Correctional Health employee, but provides consulting services in addition to his private clinic-based practice.

The following information with regard to Mr. Audette's condition was obtained from the recent meetings with his medical providers. In summary, Mr. Audette is suffering from many of the well know, and recognized effects of patients who are co-infected with HIV and Hepatitis C. The dropping CD4 levels and weight loss are recognized side effects of the Hepatitis C medication that Mr. Audette began in January of this year.

What is most important, however, is that Mr. Audette's viral load continues to be undetectable. A viral load test measures how much human immunodeficiency virus (HIV) is present in the blood. (See Exhibit 6 attached, article by Ronald Baker, PhD.). As with any patient, institutionalized or not, the co-infectious status presents a challenge for the treating physicians. Mr. Audette's physicians have in the past, and will continue in the future, to work with Mr. Audette to monitor his situation and adjust medications (to the extent possible) to fight the infection, while at the same time control his weight and minimize his pain.

Mr. Audette's CD4 Levels:

Mr. Audette's attorneys have raised the concern that his CD4 levels have dropped precipitously over the last few months. The records indicate that his CD4 was approximately 137/mm3 in February of 2005, and has dropped to 77/mm3 as of the most recent reading in April. (See Exhibit 3 attached, lab reports).

CD4 levels are indicative of the strength of an individual's immune system. (Exhibit 6). However, according to Dr. Stone, the antiviral HCV medications (specifically the Peg Interferon) that Mr. Audette started in January 2005 are known to cause a transient decrease in the CD4 level. Dr. Stone explains that once the Hepatitis medications are stopped, the CD4 levels will return to their baseline level. As noted above, the more important indicator of HIV progression is the patient's viral load. (Exhibit 6). As recently as April 25, 2005, Mr. Audette's HIV viral load was less than 75/mm3, which is clinically undetectable. (Exhibit 3). According to Dr. Stone, an undectable viral load is the "gold standard" and definitively establishes that his current HIV regimen (sustiva and DDI) is working effectively to keep the virus from duplicating and under control.

Mr. Audette's Weight:

Mr. Audette is also alleging that he has sustained rapid weight loss since January 2005, to which the defendants are acting deliberately indifferent. The records indicate that Mr. Audette weighed approximately 160 lbs. as of January 10, 2005, and weighed 147 pounds as of his most recent evaluation on May 11, 2005. (See Exhibit 4, attached, LSH consultation; Exhibit 5 attached, UMCH progress notes). Mr. Audette insists that his reduced testosterone is the cause of his weight loss, and that the defendant should increase his weight with testosterone injections. (Exhibit 2).

The records indicate that Mr. Audette's weight loss began in January, 2005, when he began the HCV therapy. (Exhibit 3). Dr. Stone explains that weight loss is also a well known side effect of the antiviral drugs used in this treatment, and is the most likely cause. Despite this, UMCH has provided the patient with a comprehensive work-up to rule out other causes of Mr. Audette's weight loss. As part of the work-up, and at the request of Dr. Stone and his treating endocrinologist, the patient's free-testosterone levels were checked. On April 5, 2005, Mr. Audette's free-testosterone came back at 1.18 ng/dl (reference 0.95-4.30 ng/dl), **within normal limits**. (Exhibit 3). Mr. Audette's thyroid, PSH, and diabetic tests also came back negative, indicating that these were not the cause of his weight loss. (Exhibit 3).

Mr. Audette has been continuously followed by an endocrinologist, with his most recent visit being on April 5th. (Exhibit 5). The endocrinologist ordered a number of laboratory tests as set forth above. She also mentioned the possibility of a pituitary adenoma, and ordered multiple labs to aid diagnosis. (Exhibit 5). The endocrinologist ultimately recommended a follow-up appointment in May, which is currently scheduled.

While Mr. Audette's physicians continue to investigate his weight loss, UMCH nutritionist, Ms. Bingham-Isaac, is treating Mr. Audette's weight loss with Resource twice a day,

and frequent snacks, in addition to his regular diet. (Exhibit 4). Ultimately, the physicians suspect that Mr. Audette's antiviral drug therapy is causing his extreme weight loss, and UMCH continues to look into other possible drug therapies to treat this ailment. At his most recent visit with Dr. McGovern, she noted her intention to discuss a possible change in the drug combination with Dr. Stone. (Exhibit 5). Mr. Audette is scheduled to be seen again this week by Dr. Stone in the infectious disease clinic.

Mr. Audette's Methadose Medication:

Mr. Audette is also alleging that Dr. Lorraine Hazard stopped his methadose pain medication in violation of his Eighth Amendment rights. There is apparently a very current debate in the medical world as to whether methadose, a pain medication, reduces the efficacy of sustiva and DDI medications, used to treat the HIV infection. Some researchers suggest that there is a connection, whereas others claim the opposite; namely, that the sustiva reduces the efficacy of the methadose. Mr. Audette asserts that the sustiva reduces the efficacy of his methadose, and thus, wants (or at least wanted at some point) his methadose increased. (Exhibit 2).

In response to the recent debate, and after consulting with a pharmacist, on March 31st, Dr. Hazard substituted plaintiff's methadose medication with Voltaren, a NSAID used to treat pain and reduce inflammation (Exhibit 4). The methadose was appropriately tapered so as to avoid any potential for withdrawal symptoms. Dr. Hazard made a clinical decision that it would be best to control the HIV virus, and attempt a different medication to treat the pain. As of April 12, 2005, the medical records suggest that Mr. Audette's concern regarding his methadose medication dwindled and he apparently told Dr. Hazard that he no longer wanted the methadose. (Exhibit 4).

Mr. Audette's Footwear:

Finally, in regards to plaintiff's footwear allegations, the defendant reiterates the facts presented in its March 2005 Opposition to Mr. Audette's original TRO. Without a doctor's order, the defendant cannot provide plaintiff with specialized footwear. The podiatrist, Dr. King, never filled out a physician order, requesting that the SBCC or UMCH purchase the special footwear for the plaintiff. While it is currently Mr. Audette's responsibility to purchase the shoes, the defendant made the necessary footwear available for plaintiff in the SBCC Canteen.

Defendant's Future Treatment Plan:

Mr. Audette's treating physicians are continually reassessing Mr. Audette's medications to ensure him the best medical treatment. The defendant continues to send plaintiff to the appropriate specialists for his HIV and Hepatitis C, and his doctors are constantly changing his medication regimen to balance all his medical needs. He will be seen this week by Dr. Stone to discuss the possibility of changing his HIV regimen, not out of any concern for his CD4 level, but rather as attempt to stabilize his weight. He will also be seen later this month by his endocrinologist to rule out the possibility of a pituitary tumor as the cause.

D. CONCLUSION

Based upon the foregoing, the defendant maintains that Mr. Audette is being appropriately treated for his complicated medical condition. The attached medical records are but a fraction of those pertaining to Mr. Audette's medical care. He is being followed closely by his primary care physicians at SBCC, as well as two infectious disease physicians, an infectious disease nurse, and an endocrinologist. There is simply no evidence to support plaintiff's claim that the defendant has been deliberately indifferent to his medical needs, or that he is being discriminated against based on his medical conditions.

Respectfully submitted,
The Defendant,
UMASS CORRECTIONAL HEALTH,
By its attorneys,

/s/ James A. Bello

James A. Bello, BBO# 633550
Lisa R. Wichter BBO# 661006
MORRISON MAHONEY LLP
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Boston, MA 02210
(617) 439-7500

I hereby certify that a true copy of the above document was served upon (each party appearing pro se and) the attorney of record for each (other) party by mail on this 16 day of MAY, 2005

/s/ James A. Bello

James A. Bello / Lisa R. Wichter

EXHIBIT 1

United States District Court
District of Massachusetts (Boston)
CIVIL DOCKET FOR CASE #: 1:05-cv-10403-DPW

Audette v. U Mass Correctional Health et al
Assigned to: Judge Douglas P. Woodlock
Cause: 42:1983 Prisoner Civil Rights

Date Filed: 02/24/2005
Jury Demand: Defendant
Nature of Suit: 550 Prisoner: Civil Rights
Jurisdiction: Federal Question

Plaintiff

Lloyd F. Audette

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V.

Defendant

U Mass Correctional Health
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Defendant

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Commissioner

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LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
02/24/2005	1	MOTION for Leave to Proceed in forma pauperis by Lloyd F. Audette. (Jenness, Susan) (Entered: 03/03/2005)
02/24/2005	2	Application for Leave to Proceed in forma pauperis by Lloyd F. Audette. (Jenness, Susan) (Entered: 03/03/2005)
02/24/2005	3	MOTION to Appoint Counsel by Lloyd F. Audette.(Jenness, Susan) Additional attachment(s) added on 3/3/2005 (Jenness, Susan). (Entered: 03/03/2005)
02/24/2005	4	MOTION for Service by Certified Mail by Lloyd F. Audette.(Jenness, Susan) (Entered: 03/03/2005)
02/24/2005	5	COMPLAINT against U Mass Correctional Health, Kathleen M. Dennehy Filing fee: $ 0.00, receipt number 0.00, filed by Lloyd F. Audette. (Attachments: # 1 Civil Cover Sheet and Category Sheet (Jenness, Susan) Additional attachment(s) added on 3/7/2005 (Jenness, Susan). (Entered: 03/03/2005)
02/24/2005	6	MOTION for Ex Parte Temporary Restraining Order by Lloyd F. Audette.(Jenness, Susan) Additional attachment(s) added on 3/7/2005 (Jenness, Susan). (Entered: 03/03/2005)

03/07/2005		Judge William G. Young : Electronic ORDER entered denying 6 Motion for TRO: The ex parte motion for temporary restraining order is denied. Prompt service is directed to be made onthe defendants. By March 17, 2005, the defendants shall submit to the Court a full copy of the plaintiff's medical records and such other supporting materials as the parties may wish. The parties are directed to Kane v. Winn, 319 F. Supp. 2d 162 (D. Mass. 2004) for a discussion of the issues presented by this complaint. (Greenberg, Rebecca) (Entered: 03/07/2005)
03/08/2005	7	Judge Douglas P. Woodlock : ORDER entered granting 2 Motion for Leave to Proceed in forma pauperis, granting 1 Motion for Leave to Proceed in forma pauperis: The Clerk shall issue summonses and the United States Marshal shall serve a copy of the summons, complaint, and this order upon defendant(s) as directed by plaintiff with all costs of service to be advanced by the United States. (Greenberg, Rebecca) (Entered: 03/08/2005)
03/08/2005	8	Judge Douglas P. Woodlock : MEMORANDUM AND ORDER entered re: 3 Motion to Appoint Counsel, 4 Motion service by certified mail: Plaintiff's Application to Proceed in forma pauperis is Allowed. Plaintiff's Motion for Service by Certified Mail is denied. Plaintiff's motion for appointment of counsel is denied without prejudice after the Defendants have filed a response to the complaint, subject to Plaintiff demonstrating how appointment of counsel is in the interests of justice in this case. (Greenberg, Rebecca) (Entered: 03/08/2005)
03/08/2005		Summons Issued as to U Mass Correctional Health, Kathleen M. Dennehy (with USM forms and instructions to Plaintiff). (Greenberg, Rebecca) (Entered: 03/08/2005)
03/08/2005	9	NOTICE: re payment of fee (prisoner filer) issued to the Treasurer at SBCC (Greenberg, Rebecca) (Entered: 03/08/2005)
03/08/2005	10	NOTICE of Appearance by David J. Rentsch on behalf of Kathleen M. Dennehy (Rentsch, David) (Entered: 03/08/2005)
03/15/2005	11	NOTICE of Appearance by James A. Bello on behalf of U Mass Correctional Health (Bello, James) (Entered: 03/15/2005)
03/16/2005	12	Medical Records received. (Nici, Richard) (Entered: 03/21/2005)
03/17/2005		Judge Douglas P. Woodlock : Electronic ORDER entered. By 3/28/05, Defendants shall electronically file a response to 6 MOTION for Temporary Restraining Order filed by Lloyd F. Audette (Rynne, Michelle) (Entered: 03/17/2005)
03/22/2005	16	SUMMONS Returned Executed Kathleen M. Dennehy served on 3/22/2005, answer due 5/5/2005. (Nici, Richard) Modified on 4/21/2005 (Nici, Richard). (Entered: 04/21/2005)
03/28/2005	13	Opposition re 6 MOTION for Temporary Restraining Order filed by U Mass Correctional Health. (Attachments: # 1 Exhibit Exhibits 1-4 to Def., UMass Opposition)(Bello, James) (Entered: 03/28/2005)

04/08/2005	14	SUMMONS Returned Executed U Mass Correctional Health served on 3/24/2005, answer due 4/13/2005. (Nici, Richard) (Entered: 04/08/2005)
04/12/2005	15	*UMass Correctional Health's* ANSWER to Complaint with Jury Demand by U Mass Correctional Health.(Bello, James) (Entered: 04/12/2005)
04/21/2005	17	MOTION to Correct 16 Summons Returned Executed by Kathleen M. Dennehy. (Attachments: # 1)(Rentsch, David) (Entered: 04/21/2005)
04/21/2005		Judge Douglas P. Woodlock : Electronic ORDER entered granting 17 Motion to Correct (Nici, Richard) (Entered: 04/21/2005)
04/21/2005		Notice of correction to docket made by Court staff. Correction: Answer due date on entry #16 corrected because: The wrong date of execution was entered. (Nici, Richard) (Entered: 04/22/2005)
04/29/2005	18	ANSWER to Complaint with Jury Demand by Kathleen M. Dennehy. (Rentsch, David) (Entered: 04/29/2005)
05/02/2005	19	REPLY to Response to Motion re 6 MOTION for Temporary Restraining Order filed by Lloyd F. Audette. (Nici, Richard) (Entered: 05/04/2005)
05/02/2005	20	Plantiff's renewed Motion for restraining order by Lloyd F. Audette. (Nici, Richard) Modified on 5/4/2005 (Nici, Richard). (Entered: 05/04/2005)
05/02/2005	21	Plantiff's MOTION to Amend Pleadings include other parties by Lloyd F. Audette.(Nici, Richard) (Entered: 05/04/2005)
05/02/2005	22	MOTION for leave to proceed to amend Complaint by Lloyd F. Audette. (Nici, Richard) (Entered: 05/04/2005)
05/02/2005	23	Plantiff's MOTION to Strike Defendant's affirmative defenses by Lloyd F. Audette.(Nici, Richard) (Entered: 05/04/2005)
05/02/2005	24	MOTION to Appoint Counsel by Lloyd F. Audette.(Nici, Richard) (Entered: 05/04/2005)
05/02/2005	25	AFFIDAVIT of Lloyd F. Audette by Lloyd F. Audette. (Nici, Richard) (Entered: 05/04/2005)
05/02/2005	26	Letter/request (non-motion) from Lloyd F. Audette. (Nici, Richard) (Entered: 05/04/2005)
05/09/2005		Judge Douglas P. Woodlock :Electronic ORDER entered granting 24 Motion to Appoint Counsel. Pro Bono counsel appointed: Brandon L. Bigelow for Lloyd F. Audette. (Greenberg, Rebecca) (Entered: 05/09/2005)
05/09/2005	27	Judge Douglas P. Woodlock : ORDER FOR APPOINTMENT OF PRO BONO COUNSEL entered. This matter is before the Court on the request of plaintiff's for the appointment of counsel to serve pro bono. There being sufficient cause to exercise the discretionary power of the Court to appoint counsel, it is ORDERED that Bingham McCutchen LLP, 150 Federal Street, Boston, MA 02110 is appointed to represent the plaintiffs

		under the provisions of the United States District Court Plan for the Appointment of Counsel For Indigent Parties in Civil Cases, unless this appointment is declined by written notice (copy to pro bono coordinator) within twenty-one (21) days from the date of this Order. Once this order takes effect, appointed counsel or his or her designated associate(s) shall serve until the litigation is terminated or the Court enters an order revoking said appointment. This appointment is limited solely to those matters at issue in this case. Counsel is not being appointed to represent the plaintiffs generally or in any other proceeding. [Contact: Brandon L. Bigelow, Esq.]. (Greenberg, Rebecca) (Entered: 05/09/2005)
05/09/2005		ELECTRONIC NOTICE of Hearing: Status Conference set for 5/19/2005 02:30 PM in Courtroom 1 before Judge Douglas P. Woodlock. Status report due 5/16/05.(Rynne, Michelle) (Entered: 05/09/2005)
05/10/2005	28	NOTICE of Appearance by Brandon L. Bigelow on behalf of Lloyd F. Audette (Bigelow, Brandon) (Entered: 05/10/2005)
05/10/2005	29	NOTICE of Appearance by Rheba Rutkowski on behalf of Lloyd F. Audette (Rutkowski, Rheba) Additional attachment(s) added on 5/13/2005 (Nici, Richard). (Entered: 05/10/2005)
05/10/2005	30	NOTICE of Appearance by Donald J. Savery on behalf of Lloyd F. Audette (Savery, Donald) (Entered: 05/10/2005)
05/10/2005	31	NOTICE of Appearance by Thomas Peter R. Pound on behalf of Lloyd F. Audette (Pound, Thomas) (Entered: 05/10/2005)
05/10/2005		NOTICE OF RESCHEDULING: Status Conference reset for 5/24/2005 02:30 PM in Courtroom 1 before Judge Douglas P. Woodlock. (Rynne, Michelle) (Entered: 05/10/2005)
05/13/2005		Notice of correction to docket made by Court staff. Correction: entry #29 corrected because: Replaced unsigned document for a signed document (Nici, Richard) (Entered: 05/13/2005)

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Description:	Docket Report	**Search Criteria:**	1:05-cv-10403-DPW
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EXHIBIT 2

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

05-10403DPW

LLOYD F. AUDETTE,
Plaintiff,

V.

UMASS CORRECTIONAL HEALTH SERVICES,
A Commonwealth Health Care Program,
Defendant, et al

PLAINTIFF'S RENEWED MOTION FOR RESTRAINING ORDER

Plaintiff moves this Honorable Court to reconsider the denial of his Motion For A Temporary Restraining Order. As grounds, the Plaintiff states that the defendants are acting in retaliation to his exerting civil remedy. (see attached amended complaint)

Plaintiff also submits his memorandum of case law in responce to Defendants oppasition which cleary justifies the renewal of this maotion.

April 14, 2005

Respectfully submillte,

The Plaintiff,

Lloyd F. Audette

Lloyd F. Audette, pro-se
S.B.C.C./P.O. Box 8000
Shirley MA 01464

UNITED STATES OF AMERICA
FOR THE DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 05-10403-DPW

LLOYD F. AUDETTE,
Plaintiff,

v.

UMASS CORRECTIONAL HEALTH,
A Commonwealth Medicine Program,
Defendant, and

DEPARTMENT OD CORRECTION,
Kathleen M. Dennehy, Commissioner
Defendant,

PLAINTIFF'S RESPONSE TO
UMASS CORRECTIONAL HEALTH'S
OPPOSITION TO PLAINTIFF' MOTION FOR
TEMPORARY RESTRAINING ORDER
AND REQUEST FOR HEARING

Now comes the Plaintiff Lloyd F. Audette in the above entitled action and hereby responds to the Defendant's response for Plaintiff's Motion for Temporary Restraining Order.

The Plaintiff states that his medical conditions have not been appropriately treated at all times, that Charlie Black knowingly lied in his statement to the Defendant's Attorney James A. Bello and that the defendant is deliberate to Plaintiff's medical needs and has now acted in retaliation to Plaintiff filing civil remedy.

RELEVANT FACTS

1. Plaintiff, pro-se inmate incarcerated at the S.B.C.C. facility agrees that defendant acknowledges he suffers from AIDS, Hepatitis C, Zollinger Ellison Syndrome, and multiple orthapedic injuries.

2. To date, Plaintiff now weighs 142 lbs. and is still losing weight.

3. The records will show that Plaintiff was receiving testosterone and oxandrolone prior to his incarceration due to AIDS waisting syndrome caused by a low CD4 count.

4. Plaintiff did see Dr. King and Defendant states that Dr. King negated in his duties to order proper footware.

5. Plaintiff is not responsible to provide his own medical treatment when incarcerated, even if he weren't indigent, which he is.

6. Health Service Administrator lied to Attorney James A. Bello in that SUSTIVA AND DDI are not Hepatitis C medications, they are AIDS medications and that SUSTIVA in fact blocks the absorbtion of methadone into the bloodstream decreasing its efficacy not the other way around as Charlie Black would have the court believe(see attached SUSTIVA literature)

7. Defendant's have used Retaliation tactics by stopping the plaintiff's methadone treatment and decreasing it by half, 20 mg. per day for the first two days and then 10 mg. per day then lower to zero knowing that this type of reduction will cause

severe withdrawals and put the Plaintiff's health at jeopardy.

PRELIMINARY INJUNCTION STANDARD

"The purpose of a preliminary injunction is to preserve the status quo so as to permit the trial court, upon full adjudication of the case's merits, more effectively to remedy discerned wrongs." CMM Cable Rep., Inc. v. Ocean Coast Properties, 48 F.3d 618,620 (1st Cir. 1995)(Citing Chalk v. United States Dist. Court. 840 F.2d 701,704(9th Cir. 1988); American hosp. Ass'n v. Harris, 625 F.2d 1328,1330 (7th Cir. 1980)). "The court's interim injunctive decree attempts to prevent further injury by maintaining the status quo, thus enhancing the court's ability, if it untimely finds for the movant, to minimize harmful effects of the defendant's wrongful conduct." Id (citation omitted).

A four part test must be taken into account to determine granting or denying a preliminary injunction, (1) the movant's likelihood of success on the merits, (2) the potential for irreparable injury, (3) a balancing of the relevant equities, and (4) the effect on the public interest.

PLAINTIFF'S LIKELIHOOD OF SUCCESS ON THE MERITS

Plaintiff claims stem from being disabled under the ADA which defines a disability as be a person with AIDS, arthritis, neuropathy, nerve damage etc. (disfigurement).

Definition under 42 USCA § 12102:

(2) Disability

The term disability means with respect to an individual-

(A) a physical or mental impairment that substantially limits one or more of the major life activities of such individual.

Further, the defendant's do not contest that the Plaintiff is disabled within the meaning of the statute. see Roth v. Lutheran General Hospital, 57 F.3d 1446,1454(7th Cir. 1995).

Plaintiff's likelihood of success depends on whether or not he can verify his claims for relief. Mass. Gen. Laws 111 § 72F states the meaning of Neglect:

Neglect, the failure to provide goods and services necessary to avoid physical harm.

Because of the very fact of incarceration, the Supreme Court has recognized that "[i]t is but just that the public be required to care for the prisoner, who cannot by reason of the deprivation of liberty, care for himself." Estelle v. Gamble, 429 U.S. 97 (1976)(citations omitted). Prison officials are more than merely negligent if they deliberately defy the express instructions of prison doctors. Martinez v. Mancusi, 443 F.2d 921,924 (2d Cir. 1970), Id at 104-05, 97 S.Ct. at 291, see also Kelly v. McGinnis, 899 F.2d 612; ("If [ ], deliberately interfered with his medically prescribed treatment for the purpose of causing him unnecessary pain,[ ], could be subject to liability even though he suffered no apparent injury, See e.g Gill v. Mooney, 824 F.2d 192 (2d Cir. 1987)

Prison officials denied Plaintiff both A.M and P.M. snacks on numerous occasions after the doctor's order was faxed, refaxed, and refaxed while Plaintiff continually lost body weight. see Affidavit attached hereto.

Plaintiff's Eighth Amendment claims are meritorious when "the evloving standards of decency that mark the progress of a maturing society." Trop v. Dulles, 78 S.CT at 598, see also Gregg v. Georgia, 428 U.S. 153 at 172-173(1976) Regardless of how evidenced, deliberate indifference to a prisoner's serious illness or injury state a cause of action under §1983, Estelle v. Gamble, 429 U.S. 97 (1976) or which involve "the unnecessary and wanton infliction of pain." Weems v. United States, 217 U.S. 349(1910) ("repeated examples of negligent act which disclose a pattern of conduct by the prison medical staff" can sufficiently evidence deliberate indifference, Kelly v. McGinnis, 899 F.2d 612 (C.A. 7(III)1990); Wellman 715 F.2d at 272 (quoting Ramos, 639 F.2d 559, 575 (10th Cir. 1980), cert denied 450 U.S. 1041 (1981)

When prison authorities deny reasonable requests for medical treatment, such denial exposes the inmate "to undue suffering or the threat of tangible residual injury." Westlake v. lucas, 537 F.2d 857,869 . Short of absolute denial "if medical treatment [i]s delayed for non-medical reasons, a case for deliberate indifference has been made out" Ancota v. Prison Health Servs., 769 F.2d 700; accord Archer v. Dutcher, 733 F.2d 14 (2d Cir.

1984)(allegation that emergency medical care to pregnant inmate was delayed in order to make her suffer states a claim of deliberate indifference under Estelle). Deliberate indifference is also evident where prison officials erect arbitrary and burdensome procedures that "result [] in interminable delays and outright denials of medical care to suffering inmates." Todaro v. Ward, 565 F.2d 48,53 (2d Cir. 1977). Prison officials may not, with deliberate indifference to the serious medical needs of the inmate, opt for "'an easier and less efficacious treatment'" of the inmates condition. West, 571 F.2d at 162 (citations omitted). Nor may they condition provision of needed medical services on the inmates ability or willingness to pay. See Ancata, 769 F.2d at 704; cf. City of Revere, 463 U.S. 239 (1983)(right to treatmentconstitutionally mandated regardless of who pays for treatment). Finally, deliberate indifference is demonstrated "[w]hen ... prison authorities prevent inmate from receiving recommended treatment for serious medical needs or deny access to physician capable of evaluating the need for such treatment." Inmates of Allegheny Jail v. Pierce, 612 F.2d 754,762 (3d Cir. 1979).

A medical need is "serious", in satisfaction of the second prong of the Estelle test, if it is "one that has been diagnosed by a physician as requiring treatment or one that a lay person would easily recognize the necessity for a doctor's attention." Pace v. Fauver, 479 F. Supp. 456,458 (D.N.J.1979), aff'd,

649 F.2d 860 (3d Cir. 1981); accord Laaman v. Helgemoe, 437 F. Supp 269,311(D.N.H.1977). The seriousness of an inmate's medical needs may also be determined by reference to the effect of denying the particular treatment. For instance, Estelle makes clear that if "unnecessary and wanton infliction of pain," 429 U.S. at 103, 97 S.Ct at 290, results as a consequence of denial or delay in the provision of adequate medical care, the medical need is of the serious nature contemplated by the eighth amendment. See id at 105, 97 S.Ct. at 291. In addition, where the denial or delay causes the inmate to suffer a lifelong handicap or permanent loss, the medical need is serious. See, e.g. Archer, 733 F.2d at 16 (pregnant inmate who miscarried stated cognizable claim where she claimed that defendants intentionally delayed emergency medical aid in order to make her suffer); Ramos v. Lamm, 639 F.2d 559,576(10th Cir. 1980) (delay in providing oral surgery resulted in "continued and unnecessary pain and loss of teeth"), cert. denied, 450 U.S. 1041(1981); Laaman, 437 F. Supp. at 312 (denial of treatment may result in permenant damage or require corrective surgery).

In the case at bar, the Plaintiff has been denied orthopedic footware because he is unable to pay for them. He has been denied follow up physical therapy for his left knee although is was ordered and it is now possible that he will need another orthoscopic surgery to correct the knee, an MRI needs to be ordered although it has not been. Plaintiff was denied proper

evaluation and treatment for a serious weight loss problem and had to wait over one year after constantly complaining about it to receive scheduling with the endocrine clinic. Plaintiff had to wait over one year to start Hepatitis C treatment after all tests and biopsies were completed. Plaintiff was dispensed six percosets per day for pain when the doctor ordered oxicodone because the plaintiff could not tollerate the tylenol in the percosets and when the mistake was discovered some six months later, Plaintiff was placed on methadone without the drug interactions being checked in advance. Plaintiff brought to the defendant's attention that SUSTIVA, an HIV(AIDS) medication caused the methadone not to absorb into the patients bloodstream.

Both SUSTIVA and VIRAMUNE are known as nonnucleoside reverse transcriptase inhibitors or (nonnukes). Viramune causes blood-based methadone levels to fall by an average of 29%, but the absorbtion rate as much as 70% in some HIV patients. The literature states that the methadone should be increased to prevent drug withdrawal symptoms (see exhibit).

Instead of increasing the methadone as recommended, the defendants arbitrarily are decreasing the doses at an unsafe rate to intentionally cause the plaintiff to suffer severe withdrawal symptoms as an act of retaliation against plaintiff. Methadone withdrawals can last up to several months depending on the dosage and length of time the patient was receiving methadone treatment.

In Johnson v. Summers, , 411 Mass 92 at 86 the standard of review is set forth as being whether the evidence in light most favorable to the plaintiff, "anywhere in the evidence, from whatever source derived, any combination of circumastance could be found from which a reasonable inference could be drawn in favor of the plaintiff." Miga v. Holyoke, 398 Mass. 343,348 (1986). Poirier v. Plymouth, 374 Mass. 206,212 (1978), quoting Raunela v. Hertz Corp., 361 Mass. 341,343 (1972).

A §1983 plaintiff must demonstrate that (1) a person acting under color of State law commited the conduct complained of and (2) the conduct deprived the plaintiff of a right, privilege or immunity secured by the Constitution or laws of the United States. Parratt v. Taylor, 451 U.S. 527, 535 (1981).

The United States Supreme COurt held that "deliberate indifference to serious medical needs" of convicted prisoners violates the proscription of cruel and unusual punishment stated in the Eighth Amendment to the United States Constitution. Estelle v. Gamble, 429 U.S. 97 (1976).

The Supreme Court stated that § 1983 "creates a species of tort liability," Imbler v. Pachtman, 424 U.S. 408 (1976) and that sctions under the statuce sre governed by common law tort principles. See Cary v. Piphus, 435 U.S. 247, 2570259 (1978). A showing of proximate cause is a necessary elememt in a § 1983 action, See Daniels v. Gilbreath, 668 F.2d 1350,1355 (9th Cir. 1985), and that causation is ordinnarily for the jury Zezuski v. Jenny Mfg. Co., 363 Mass. 324,328 (1973). "A plaintiff

need only show 'that there was greater likelihood or probability that the harm complained of was due to causes for which the defendant was responsible than any other cause.'" Mullins v. Pine Manoe College, 389 Mass. 47,58 (1983). It must be shown how ever, that a defendant's negligent conduct is a "substantial factor" in bringing about the harm to the plaintiff. Restatement (Second) of Torts § 431 (1965).

The plaintiff has already established essential elements of his claim "either by direct evidence or rational inference of probabilities from established facts." [411 Mass. 92] Zezuski v. Jenny Mfg. Co., by a showing of the medical records which verify the Plaintiff's steady weight loss without receiving treatment for over one year for it, and by the physicians notes verifying that Plaintiff is in need of special footware and none was ordered, and that percosets were given to the Plaintiff for six months when oxicodone was prescribed and that methadone was prescribed to try to correct the neglegent medical order. The Plaintiff can also show that the defendants are acting in a retalitory manner by eliminating all pain medication to date. The Plaintiff's likelihood of success on the merits are strong once all the discovery process is completed, and the Plaintiff will also be able to show a blatent and continual neglect on the part of the defendants toward all inmates medical needs. The medical records, when viewed in light most favorable to the plaintiff will show his success is inevitable.

For the reasons stated herein and the case law supporting the Plaintiff's claims he is likely to prevail on his claims for success on the merits and should therefore be granted an immediate Restraining Order against the defendants restraining them from harming him any further and correcting the immediate medical needs of the plaintiff.

Rather, because plaintiff's request for a TRO was denied, and because he filed a grievance about experiencing withdrawal symptoms, defendants are acting in retaliation against the Plaintiff for exerting his civil rights to proper medical care.

Plaintiff requests an immediate hearing on the issues for an injunction or in the alternative a Temporary Restraining Order before the withdrawal symptoms put the plaintiff's health at further jeapordy.

WHEREFORE, for the foregoing reasons, the Plaintiff respectfully requests this Motion for a Temporary Restraining Order be allowed.

I hereby certify that a true copy of the above document was served upon each party, attorney of record by mail this 7th day of April 2005.

Lloyd F. Audette

Lloyd F. Audette

Respectfully submitted,
By the Plaintiff, pro-se

Lloyd F. Audette
S.B.C.C./P.O. Box 8000
Shirley MA 01464

EXHIBIT

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO.: 05-10403DPW

LLOYD F. AUDETTE,
Plaintiff,

V.

UMASS CORRECTIONAL HEALTH,
A Commonwealth Medicine Program,
Defendant, and

DEPARTMENT OF CORRECTON
Kathleen M. Denney, Commissioner,
Defendant.

AFFIDAVIT OF JAMES A. BELLO

I, James A. Bello, being duly sworn, hereby depose and state the following:

1. I am a partner at the law firm of Morrison Mahoney, with offices located at 250 Summer Street, Boston, Massachusetts 02210. I am duly licensed to practice law and I am in good standing in the Commonwealth of Massachusetts.

2. I am counsel for defendant, UMASS Correctional Health ("UMCH"), in the above referenced matter. I have personal knowledge of all facts set forth herein and I am familiar with plaintiff's allegations and the procedural history of this case.

3. I spoke with Health Service Administrator for the Souza-Baranowski Correctional Center ("SBCC"), Charlie Black, on March 25, 2005. During this telephone conversation, we discussed the status of plaintiff, Lloyd Audette's, medical treatment. Specifically, Mr. Black addressed the five requests included in plaintiff's Motion for a Temporary Ex Parte Restraining Order.

5. Regarding plaintiff's first request, Mr. Black told me that a podiatrist, Dr. King, recommended plaintiff wear Rockport walking shoes to help remedy his bone spur. Mr. Black noted that Dr. King never filled out a physician's order, requesting that the Department of Correction ("DOC") pay for these shoes. In response to the doctor's recommendation, Mr. Black ordered the Rockport walking shoes for the DOC Canteen. These shoes are now available at the Canteen for plaintiff's purchase at his discretion.

6. When addressing plaintiff's second request, Mr. Black pointed out that Dr. Stone, the infectious disease specialist at the SBCC, had concerns about treating Mr. Audette with testosterone injections, given his history of HIV and Hepatitis C. Mr. Black informed me that plaintiff Audette was not receiving testosterone upon his arrival at SBCC, in February of 2004. Nevertheless, defendants still scheduled an appointment with the endocrinologist for the near future, so that plaintiff can be evaluated for testosterone therapy.

7, Mr. Black also noted that when plaintiff meets with the endocrinologist, his third request, for Oxandorlone medication, will also be discussed. Mr. Black informed me that even though Audette never requested this medication from the SBCC, UMCH will still consult with the endocrinologist as to the effectiveness of this type of anabolic steroid treatment.

8. Mr. Black and I also discussed plaintiff's fifth request for an increase in his methadose medication. Mr. Black mentioned that Dr. Stone expressed concern for plaintiff's health, given that Mr. Audette also receives Sustiva and DDI medication for his Hepatitis C. Specifically, Dr. Stone noted that literature warns of declined efficacy in the Hepatitis C drugs if the level of methadose is too high. Wary about offsetting the

balance in plaintiff's medical treatments, Mr. Black told me that on April 4, 2005, plaintiff will be seen in the Infectious Disease Clinic at which point the issue will be addressed. not done to date April 7, 2005

9. The above statements are true and accurate and based upon my personal knowledge.

SIGNED UNDER THE PAINS AND PENALTIES OF PERJURY

THIS 25 DAY OF MARCH, 2005.

James A. Bello (BBO# 633550)

AFFIDAVIT

I Russ Michael Dagenais, do hereby depose and say that the foregoing statements are true and accurate to the best of my knowledgs and recollection.

1. My name is Russ Michael Dagenais.

2. I am an inmate housed at the Souza Baronowski Correctional Center and was housed there on the date in question.

3. That on or about the week of February 18, 2005, I witnessed inmate Lloyd Audette argueing with the kitchen lieutenent Sid Johnson because he did not receive an A.M. snack.

4. I witnessed Lt. Sid Johnson refuse to give inmate Audette an A.M. snack and after inmate Audette walked away from diet window I heard Lt. Sid Johnson laugh and state to the other officers, "I don't care what the order states, I don't think he needs a snack and I'm not going to give him one."

5. That the table I sit at in the chow hall is only a few feet away from the diet window and I can both clearly see and hear with clarity everything that was said at the diet window.

6. I also witnessed inmate Audette try to give Lt. Sid Johnson a copy of the diet order he took out of his pocket and Lt. Sid Johnson refused to accept it while stating, "Have it faxed to me."

7. Inmate Audette then stated that he had medical fax the order to him four times that week and then Lt. Sid Johnson stated, "Well, I guess that I don't have a fax machine."

8. There were other occassions that I witnessed similar events take place between inmate Audette and Lt. Sid Johnson but I don't recall the exact dates or words involved, but it always stemmed from inmate Audette being refused an A.M. snack from the kitchen.

9. From what I observed, it seemed to be an on going problem between inmate Audette and the kitchen lieutenent Sid Johnson in not providing inmate Audette with dietary snacks.

Signed under the penalties of perjury on this the 19TH day of MARCH, 2005.

Russ Michael Dagenais

Inmate Grievance and Appeal Form

Facility:

Grievance ☐ Date:

Inmate First Name: ID#:

Appeal ☐ Date:

Inmate Last Name: Date of Birth: Housing Unit:

Summary of Grievance, or Reason for Appeal: (Attach Additional Sheets As Necessary)

I spoke to Mindy the INfectious Desease nurse more than once and also showed her literature verifying that one of the HIV medications I am on, SUSTIVA, has a blocker in it that stops methadone from absorbing into my bloodstream and that I have been getting no effect from the methadone and am experiencing withdrawals from it every day. She told me she spoke to Dr. Hazard and she too agrees that sustiva does this but the problem was not resolved. I am either deemed to suffer in pain and withdrawals or stop taking my HIV medication. This is unacceptable. I still have not gotten any results regarding the weight loss problem that has been goin on for one year to date. I have lost a total of 45 pounds and still have not been evaluated for testosterone treatment as I was receiving on the street. I am also filing a complaint with the Board of Registration of Medicine as well as sending a copy of this grievance to the COmmissioner and to the Clerk of Court.

Remedy Requested (Attach Additional Sheets As Necessary):

Correct this problem**TODAY, TOMORROW IS UNACCEPTABLE!!!**

Inmate Signature: Lloyd Audette **Date:** March 28 2005

Health Services Unit Use Only

Date Received:		Staff Recipient:		Routed To:	

cc. Katheleen M. Dennehy
Clerk Federal Court/ Audette v. UMASS et al No. 05-10404-DPW

DRUG NAME & MAKER	SUGGESTED DOSAGE	KNOWN SIDE EFFECTS	RECOMMENDATIONS & WARNINGS
[redacted]	Twice daily subcutaneous injections from single-use vials.	Serious allergic reactions, such as trouble breathing, fever with vomiting and a skin rash, blood in urine, and swelling of feet. Also local skin reactions at the site of injection.	Watch for symptoms of bacterial pneumonia, such as cough with fever, rapid breathing, and shortness of breath. Consult a physician immediately if signs of a serious allergic reaction or pneumonia develop. Also watch for infection at site of injections.

DRUG NAMES & MAKER	SUGGESTED DOSAGE	KNOWN SIDE EFFECTS	RECOMMENDATIONS & WARNINGS
[redacted]	400 mg (either four 100 mg or two 200 mg tablets) three times a day.	Rash (indicating life-threatening Stevens-Johnson syndrome in rare cases). If rash develops, contact physician.	Take with cranberry or orange juice if you have low stomach acid. Benadryl or topical corticosteroids may relieve rash symptoms. One study shows women may have higher blood levels of Rescriptor.
	One 600 mg tablet a day. For ages 3 and up.	Light-headedness, sleeplessness, dizziness, body ache, rash, headache, diarrhea, nausea, elevated liver enzymes. Vivid dreams often associated.	If a problem, take before bedtime to avoid nervous system side effects and light-headedness. Drug penetrates blood-brain barrier. Warning: not for use in pregnancy. Take on an empty stomach.
	One 200 mg tablet twice a day.	Fever, muscle soreness, elevated liver function, rash (possibly indicating life-threatening Stevens-Johnson syndrome in rare cases).	If rash develops, call your doctor; Benadryl or topical corticosteroids may relieve rash symptoms. Drug crosses the placenta. Take with or without food. Monitor liver functions closely during first 12 weeks.

DRUG NAME & MAKER	SUGGESTED DOSAGE	KNOWN SIDE EFFECTS	RECOMMENDATIONS & WARNINGS
[redacted]	Two tablets a day.	See Epivir (3TC) and Retrovir (AZT).	Watch for anemia and myopathy (muscle pain). Also associated with bone marrow problems.
	One 200 mg a day.	Headache, diarrhea, nausea, rash.	Take with or without food. Reduction of dosage is recommended for patients with impaired kidney function.
	One 300 mg a day or two 150 mg/day.	Headache, nausea, fatigue, low white-blood-cell count, congestion, runny nose, hair loss (rare), neuropathy.	Watch for anemia. Monitor triglycerides for pancreatitis, especially in children. Take with or without food. Synergistic antiviral effect reported when combined with Crixivan and AZT.
	One tablet once a day.	Headache, nausea, fatigue, low white-blood-cell count, neuropathy, rare allergy, abdominal pain, and gastrointestinal and liver problems.	Watch for hypersensitivity reaction associated with abacavir-containing medications. Should not be used by patients who have exhibited symptoms of hypersensitivity to abacavir. No food restrictions.
	One 0.75 mg tablet every eight hours.	Skin rashes, canker sores, inflammation of mouth, nausea, neuropathy, upset stomach, pancreatitis, liver damage.	Avoid taking with food if possible.
	600 mg a day (two 300 mg tablets or six 100 mg capsules).	Nausea, vomiting, anemia, low white-blood-cell counts, bone marrow damage, headaches, rash, itching, weakness, loss of appetite.	Best on empty stomach; take AZT with food if you have stomach irritation. Watch for anemia and neutropenia. Warning: A structural flaw in AZT may lead to HIV resistance. No food restrictions.
	One capsule twice a day.	See Epivir (3TC), Retrovir (AZT), and Ziagen (abacavir).	Should not be prescribed for anyone who weighs less than 88 pounds or other patients requiring dose adjustments. Permanently discontinue if hypersensitivity to abacavir cannot be ruled out after the onset of the common side effects. No food restrictions.
	One capsule once a day.	Granted accelerated approval by FDA; final safety and efficacy studies are ongoing.	Existing data from the use of Viread (tenofovir disoproxil fumarate) and Emtriva (emtricitabine) have been extrapolated for current recommendations and warnings. [CONTINUES]

Evidence

DRUG NAME & MAKER	SUGGESTED DOSAGE	KNOWN SIDE EFFECTS	RECOMMENDATIONS & WARNINGS
[redacted]	Patients weighing ≥60 kg (132 lbs) take one 400 mg once a day; <60 kg take one 250 mg once a day.	Stomach pain, diarrhea, pancreatitis, hepatitis, seizures, headaches; neuropathy with high doses.	Avoid alcohol, which increases risk of pancreatitis. Take on empty stomach at least 30 minutes before meal. Increased risk of pancreatitis with d4T and possibly hydroxyurea.
	One 300 mg tablet a day.	Elevated creatine phosphoskinase and transaminases. Diarrhea, nausea, vomiting. Possible bone toxicity.	This medication is a nucleotide reverse transcriptase inhibitor. Watch for lactic acidosis and hepatomegaly with steatosis (severe liver enlargement and excess fat in the liver). No food restrictions.
	Patients weighing ≥60 kg (132 lbs) take one 40 mg twice a day; <60 kg take one 30 mg twice a day.	Neuropathy, pancreatitis, insomnia, hyperactivity, elevated liver enzymes, and anemia at high doses.	Watch for neuropathy and pancreatitis. Watch for signs of lactic acidosis; permanent discontinuation should be considered in confirmed cases. No food restrictions.
	One 300 mg tablet twice a day.	Headache, fatigue, rare allergy (fever, rash, nausea, dizziness, vomiting), abdominal pain, and gastrointestinal and liver problems. Allergy may be signs of serious hypersensitivity.	Stop drug immediately if any sign of allergy occurs. Do not resume treatment after reaction; fatal reactions have been reported after treatment was resumed. Avoid during pregnancy. Abacavir Hypersensitivity Registry has been established: (800) 270-0425. No food restrictions.

DRUG NAME & MAKER	SUGGESTED DOSAGE	KNOWN SIDE EFFECTS	RECOMMENDATIONS & WARNINGS
[redacted]	Eight 150 mg capsules twice a day.	Nausea, gas, headache, neuropathy, rash, diarrhea, mouth numbing, fatigue. Rare: Stevens-Johnson syndrome.	Contains high levels of vitamin E. Consult with your doctor about possible interactions with vitamin E supplements or blood-thinning drugs. Take with or without food but avoid high-fat meals.
	Two 400 mg capsules every eight hours.	Kidney stones, anemia; rarely elevates liver enzymes. May increase risk of thrombosis. In rare instances, hair loss.	Take on empty stomach with water one hour before or two hours after eating. Drink at least six glasses of water daily to avoid kidney stones or consider lower dose with Norvir. Alternative liquids: juice (except grapefruit), skim milk, coffee, tea. Take with fat-free snacks.
	1,200 mg (one 400 mg and one 800 mg) boosted with 100 mg Norvir three times a day.	Diarrhea, gas, nausea, stomach cramps, heartburn, fatigue, numbness, rash, elevated liver enzymes.	Take with food or within two hours of eating. Fortovase is more potent than Invirase. Invirase not recommended as first-line therapy due to poor absorption and resistance issues.
	1,000 mg (two 500 mg tablets) boosted with one 100 mg ritonavir twice daily.	Abdominal discomfort, diarrhea, dizziness, numbness, rash. Spontaneous bleeding has occurred in patients with hepatitis A and B.	Not suggested for patients with liver problems. Take within two hours after a meal. Use of garlic capsules can reduce concentrations in the blood.
	Three (400 mg lopinavir/100 mg ritonavir coformulated) twice a day.	Nausea, skin rash, diarrhea, loose stools, elevated triglyceride and lipid levels, fatigue, and pancreatitis.	Do not take with Rescriptor or additional Norvir. Take with food.
	One 700 mg with one 100 mg of ritonavir twice a day. Or two 700 mg twice a day for protease-inhibitor–naive patients	Diarrhea, nausea, vomiting, headache, and rash.	Once daily dosing with ritonavir is not recommended for protease-inhibitor–experienced patients. Take with or without food or water. Three alternate dosing recommendations for protease-inhibitor–naive patients is available.
	One 600 mg twice a day.	Nausea, vomiting, weakness, diarrhea, rash, fatigue, numbness around mouth, changed taste in mouth, elevated liver enzymes.	Build up to optimal dose over a few days. Take with a full, high-protein meal. Yogurt may reduce side effects. Separate ddI dosing by at least two hours.
	Two 200 mg capsules once a day.	Nausea, infection, headache, vomiting, diarrhea, abdominal pain, drowsiness, insomnia, and fever.	Take with food. Watch for hyperbilirubinemia (abnormally high amounts of an orange-yellow pigment in the bile) in the blood.
	Five 250 mg two times/day or two 625 mg two times/day.	Fatigue, rash, nausea, stomach cramps, diarrhea, elevated liver enzymes.	Take with food. Use Imodium or Lomotil to control diarrhea. Dose desensitization can work for patients experiencing rash.

This side Evidence

PATIENT INFORMATION

℞ ONLY

SUSTIVA® (sus-TEE-vah) [efavirenz (eh-FAH-vih-rehnz)] capsules and tablets

ALERT: Find out about medicines that should NOT be taken with SUSTIVA.

Please also read the section **"MEDICINES YOU SHOULD NOT TAKE WITH SUSTIVA."**

Read this information before you start taking SUSTIVA (efavirenz). Read it again each time you refill your prescription, in case there is any new information. This leaflet provides a summary about SUSTIVA and does not include everything there is to know about your medicine. This information is not meant to take the place of talking with your doctor.

What is SUSTIVA?

SUSTIVA is a medicine used in combination with other medicines to help treat infection with Human Immunodeficiency Virus type 1 (HIV-1), the virus that causes AIDS (acquired immune deficiency syndrome). SUSTIVA is a type of anti-HIV drug called a "non-nucleoside reverse transcriptase inhibitor" (NNRTI). NNRTIs are not used in the treatment of Human Immunodeficiency Virus type 2 (HIV-2) infection.

SUSTIVA works by lowering the amount of HIV-1 in the blood (viral load). SUSTIVA must be taken with other anti-HIV medicines. When taken with other anti-HIV medicines, SUSTIVA has been shown to reduce viral load and increase the number of CD4+ cells, a type of immune cell in blood. SUSTIVA may not have these effects in every patient.

SUSTIVA does not cure HIV or AIDS. People taking SUSTIVA may still develop other infections and complications. Therefore, it is very important that you stay under the care of your doctor.

SUSTIVA has not been shown to reduce the risk of passing HIV to others. Therefore, continue to practice safe sex, and do not use or share dirty needles.

What are the possible side effects of SUSTIVA?

Serious psychiatric problems. A small number of patients experience severe depression, strange thoughts, or angry behavior while taking SUSTIVA. Some patients have thoughts of suicide and a few have actually committed suicide. These problems tend to occur more often in patients who have had mental illness. Contact your doctor right away if you think you are having these psychiatric symptoms, so your doctor can decide if you should continue to take SUSTIVA.

Common side effects. Many patients have dizziness, trouble sleeping, drowsiness, trouble concentrating, and/or unusual dreams during treatment with SUSTIVA. These side effects may be reduced if you take SUSTIVA at bedtime on an empty stomach. They also tend to go away after you have taken the medicine for a few weeks. If you have these common side effects, such as dizziness, it does not mean that you will also have serious psychiatric problems, such as severe depression, strange thoughts, or angry behavior. Tell your doctor right away if any of these side effects continue or if they bother you. It is possible that these symptoms may be more severe if SUSTIVA is used with alcohol or mood altering (street) drugs.

If you are dizzy, have trouble concentrating, or are drowsy, avoid activities that may be dangerous, such as driving or operating machinery.

Rash is common. Rashes usually go away without any change in treatment. In a small number of patients, rash may be serious. If you develop a rash, call your doctor right away. **Rash may be a serious problem in some children.** Tell your child's doctor right away if you notice rash or any other side effects while your child is taking SUSTIVA.

Other common side effects include tiredness, upset stomach, vomiting, and diarrhea.

Changes in body fat. Changes in body fat develop in some patients taking anti-HIV medicine. These changes may include an increased amount of fat in the upper back and neck ("buffalo hump"), in the breasts, and around the trunk. Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these fat changes are not known.

Tell your doctor or healthcare provider if you notice any side effects while taking SUSTIVA.

Contact your doctor before stopping SUSTIVA because of side effects or for any other reason.

This is not a complete list of side effects possible with SUSTIVA. Ask your doctor or pharmacist for a more complete list of side effects of SUSTIVA and all the medicines you will take.

How should I take SUSTIVA?

General information

- You should take SUSTIVA on an empty stomach, preferably at bedtime.
- Swallow SUSTIVA with water.
- Taking SUSTIVA (efavirenz) with food increases the amount of medicine in your body, which may increase the frequency of side effects.
- Taking SUSTIVA at bedtime may make some side effects less bothersome.
- SUSTIVA must be taken in combination with other anti-HIV medicines. If you take only SUSTIVA, the medicine may stop working.
- Do not miss a dose of SUSTIVA. If you forget to take SUSTIVA, take the missed dose right away, unless it is almost time for your next dose. Do not double the next dose. Carry on with your regular dosing schedule. If you need help in planning the best times to take your medicine, ask your doctor or pharmacist.
- Take the exact amount of SUSTIVA your doctor prescribes. Never change the dose on your own. Do not stop this medicine unless your doctor tells you to stop.
- If you believe you took more than the prescribed amount of SUSTIVA, contact your local Poison Control Center or emergency room right away.
- Tell your doctor if you start any new medicine or change how you take old ones. Your doses may need adjustment.
- When your SUSTIVA supply starts to run low, get more from your doctor or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to SUSTIVA and become harder to treat.
- Your doctor may want to do blood tests to check for certain side effects while you take SUSTIVA.

Capsules

- The dose of SUSTIVA capsules for adults is 600 mg (three 200-mg capsules, taken together) once a day by mouth. The dose of SUSTIVA for children may be lower (see **Can children take SUSTIVA?**).

Tablets

- The dose of SUSTIVA tablets for adults is 600 mg (one tablet) once a day by mouth.

Can children take SUSTIVA?

Yes, children who are able to swallow capsules can take SUSTIVA. Rash may be a serious problem in some children. Tell your child's doctor right away if you notice rash or any other side effects while your child is taking SUSTIVA. The dose of SUSTIVA for children may be lower than the dose for adults. Capsules containing lower doses of SUSTIVA are available. Your child's doctor will determine the right dose based on your child's weight.

Who should not take SUSTIVA?

Do not take SUSTIVA if you are allergic to the active ingredient, efavirenz, or to any of the inactive ingredients. Your doctor and pharmacist have a list of the inactive ingredients.

What should I avoid while taking SUSTIVA?

- **Women taking SUSTIVA should not become pregnant.** Serious birth defects have been seen in the offspring of animals and women treated with SUSTIVA during pregnancy. It is not known whether SUSTIVA caused these defects. **Tell your doctor right away if you are pregnant.** Also talk with your doctor if you want to become pregnant.
- Women should not rely only on hormone-based birth control, such as pills, injections, or implants, because SUSTIVA may make these contraceptives ineffective. Women must use a reliable form of barrier contraception, such as a condom or diaphragm, even if they also use other methods of birth control.
- **Do not breast-feed if you are taking SUSTIVA.** The Centers for Disease Control and Prevention recommend that mothers with HIV not breast-feed because they can pass the HIV through their milk to the baby. Also, SUSTIVA may pass through breast milk and cause serious harm to the baby. Talk with your doctor if you are breast-feeding. You may need to stop breast-feeding or use a different medicine.
- Taking SUSTIVA with alcohol or other medicines causing similar side effects as SUSTIVA, such as drowsiness, may increase those side effects.
- Do not take any other medicines without checking with your doctor. These medicines include prescription and nonprescription medicines and herbal products, especially St. John's wort.

Before using SUSTIVA, tell your doctor if you

- **have problems with your liver or have hepatitis.** Your doctor may want to do tests to check your liver while you take SUSTIVA.
- **have ever had mental illness or are using drugs or alcohol.**
- **have ever had seizures or are taking medicine for seizures** [for example, Dilantin® (phenytoin), Tegretol® (carbamazepine), or phenobarbital]. Your doctor may want to check drug levels in your blood from time to time.

What important information should I know about taking other medicines with SUSTIVA?

SUSTIVA (efavirenz) may change the effect of other medicines, including ones for HIV, and cause serious side effects. Your doctor may change your other medicines or change their doses. Other medicines, including herbal products, may affect SUSTIVA. For this reason, **it is very important to:**

- let all your doctors and pharmacists know that you take SUSTIVA.
- tell your doctors and pharmacists about all medicines you take. This includes those you buy over-the-counter and herbal or natural remedies.

Bring all your prescription and nonprescription medicines as well as any herbal remedies that you are taking when you see a doctor, or make a list of their names, how much you take, and how often you take them. This will give your doctor a complete picture of the medicines you use. Then he or she can decide the best approach for your situation.

Taking SUSTIVA with St. John's wort *(Hypericum perforatum)*, an herbal product sold as a dietary supplement, or products containing St. John's wort is not recommended. Talk with your doctor if you are taking or are planning to take St. John's wort. Taking St. John's wort may decrease SUSTIVA levels and lead to increased viral load and possible resistance to SUSTIVA or cross-resistance to other anti-HIV drugs.

MEDICINES YOU SHOULD NOT TAKE WITH SUSTIVA

The following medicines may cause serious and life-threatening side effects when taken with SUSTIVA. You should not take any of these medicines while taking SUSTIVA:

- Hismanal® (astemizole)
- Propulsid® (cisapride)
- Versed® (midazolam)
- Halcion® (triazolam)
- Ergot medications (for example, Wigraine® and Cafergot®)

The following medicine should not be taken with SUSTIVA since it may lose its effect or may increase the chance of having side effects from SUSTIVA:

- Vfend® (voriconazole)

The following medicines may need to be replaced with another medicine when taken with SUSTIVA (efavirenz):

- Fortovase®, Invirase® (saquinavir)
- Biaxin® (clarithromycin)

The following medicines may need to have their dose changed when taken with SUSTIVA:

- Crixivan® (indinavir)
- Kaletra® (lopinavir/ritonavir)
- Methadone
- Mycobutin® (rifabutin)
- REYATAZ® (atazanavir sulfate). If you are taking SUSTIVA and REYATAZ, you should also be taking Norvir® (ritonavir).
- Zoloft® (sertraline)

These are not all the medicines that may cause problems if you take SUSTIVA. Be sure to tell your doctor about all medicines that you take.

General advice about SUSTIVA:

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use SUSTIVA for a condition for which it was not prescribed. Do not give SUSTIVA to other people, even if they have the same symptoms you have. It may harm them.

Keep SUSTIVA at room temperature (77°F) in the bottle given to you by your pharmacist. The temperature can range from 59° to 86°F.

Keep SUSTIVA out of the reach of children.

This leaflet summarizes the most important information about SUSTIVA. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for the full prescribing information about SUSTIVA, or you can visit the SUSTIVA website at http://www.sustiva.com or call 1-800-426-7644.

Distributed by:

Bristol-Myers Squibb Company

Princeton, NJ 08543 USA

T4-B0001B-12-04 Revised December 2004

Based on package insert dated December 2004,
51-022486-04, 1178226A2

Evidence

INBRIEF

Viramune Can Affect Methadone Use

Adults who are HIV-positive and take an antiretroviral cocktail containing Viramune and who also are on methadone therapy to treat drug addiction might have to have their methadone doses increased because of interactions between the medications, researchers in Germany report.

The scientists examined 20 HIV patients taking both Viramune and methadone and discovered that among some of the study subjects methadone absorption into the bloodstream was severely suppressed. Blood-based methadone levels fell by an average of 29%, but absorption of the drug dropped as much as 70% in some HIV patients. All but six patients required higher methadone doses to prevent drug-withdrawal symptoms.

Because blood-based levels of Viramune were unaffected, the researchers say the medications can be prescribed together as long as methadone doses are adjusted as needed for full efficacy.

SAN FRANCISCO AND BEER IMAGES FROM PHOTOS.COM

Alcohol Increases Oral Infection Risk

Exposing cells from the mouth to alcohol—even at concentrations similar to those in beer and wine—can make them more suspectible to HIV infection, according to a study in the December 1 issue of *Journal of Acquired Immune Deficiency Syndromes*.

Researchers at the University of California, Los Angeles, Dental Institute exposed oral epithelial cells from HIV-negative adults to various concentrations of ethanol, then exposed them to a strain of HIV engineered to be easily detectable. Cells exposed to a 4% alcohol solution—similar to the concentration in beer—for 10 minutes showed a three-fold to six-fold greater susceptibility to infection than unexposed cells. Further analysis showed the boosted infection risk was linked directly to alcohol's effect on the cells and not on the virus.

The researchers say they are unclear how HIV entered the cells, since they lack a key receptor necessary for HIV attachment. They theorize, though, that alcohol either alters the cellular membranes to allow viral entry or interacts with key proteins to enable cellular fusion and infection.

[redacted]

Evidence

Can Liver Damage Lead to Diabetes?

Liver damage, as measured by abnormal levels of the liver enzyme ALT, might boost the risk for type II diabetes among HIV-positive adults, U.S. researchers note in the December 1 issue of *Journal of Acquired Immune Deficiency Syndromes.*

High body weight relative to height and genetic factors—including having diabetic relatives—also were linked with the development of the disease.

The researchers studied the records of HIV patients receiving care between 1991 and 2000 at two New York clinics. They discovered that patients who developed diabetes had significantly higher ALT levels than those who did not during the course of the study.

Doctors should closely monitor HIV patients with elevated liver enzyme levels for early signs of the onset of diabetes, the researchers conclude. Careful monitoring also should be given to overweight patients and those with a family history of the disease.

Weight Loss Is Linked to CD4 Counts

HIV-related weight loss is linked to decreasing CD4-cell counts—not to HIV viral levels—in adults taking antiretroviral drugs, according to the U.S. Nutrition for Healthy Living Study. Data from the study published in the January 1 issue of *Clinical Infectious Diseases* show that for HIV-positive adults on a successful and stable antiretroviral regimen, changes in CD4-cell counts are associated with changes in weight.

Researchers report that a CD4-cell-count drop of 100 was linked with an average weight loss of 0.35 kilogram—slightly less than one pound.

The link between CD4-cell levels and weight loss suggests that controlling viral load is not enough to prevent weight changes in HIV-positive adults taking anti-HIV drugs, the researchers conclude. Changing anti-HIV drugs to a regimen that both controls viral replication and leads to CD4-cell rebounds could help avoid the onset of HIV-related wasting or lead to a regaining of lost weight, they say.

* CD4 dropped to 137 because of all time made weren't available

LIVER IMAGE BY JOHN M. DAUGHERTY/PHOTO RESEARCHERS INC.; CONDOMS FROM NEWSCOM

IN BRIEF

[redacted]

WWW.HIVPLUSMAG.COM

write to Fields-Gardner at ccade@hivplusmag.com / ask about Testosterone Therapy [illegible]

EXHIBIT 3

UMass Memorial Medical Center
One Biotech Park
365 Plantation Street, Suite 200
Worcester, MA 01605-2376

Laboratory Report

Posted: 02/09/2005 14:51
Printed: 05/11/2005 14:42
Rpt Nbr: 01.1.3737673

Patient Name: AUDETTE,LLOYD BirthDate: 12/31/1958 Sex: M
MRN: YY000298805 Acct: YY000298805

Physician: U - Doctor,Unknown Status: REF
Location: YY-SBCC Admit: 02/08/2005

Specimen: 20050208:L00029R Coll: 02/08/2005 13:10

Ordered: CD4 - CD4 LEVELS

Test	Result		Flag	Reference
ABS CD4 - ABSOLUTE CD4	137	/mm3	L	400-1600
CD4CD8 RATIO - CD4:CD8 RATIO	0.28		L	1.20-2.40
%CD4 - %CD4	15	%	L	29-61
%CD8 - %CD8	54	%	H	14-32
%CD3 - %CD3	70	%		56-84

INTERPRETAT - INTERPRETATION
REDUCED CD4 CELLS.

<<< End of text >>>

UMass Memorial Medical Center
One Biotech Park
365 Plantation Street, Suite 200
Worcester, MA 01605-2376

Laboratory Report

Posted: 04/08/2005 02:00
Printed: 05/11/2005 14:42
Rpt Nbr: 01.1.4267484

Patient Name: AUDETTE,LLOYD BirthDate: 12/31/1958 Sex: M
MRN: LS00056059 Acct: ZS0000003959

Physician: ZZ,SHAT - HOSPITAL,LEMUEL Status: REF
Location: ZZ-SHATM Admit: 04/05/2005

PV2

Specimen: 20050405:RL00129R Coll: 04/05/2005 00:01

Ordered: FREET - TESTOSTERONE, FREE

Test	Result	Flag	Reference
FREET - TESTOSTERONE FREE	1.18 ng/dL		0.95-4.30

REFERENCE RANGE for Testosterone Free
Males:
20-49 yrs . . . . 0.95-4.30 ng/dL
> or = 50 yrs . . . 0.80-3.50 ng/dL
Females:
Ovulating . . . . Up to 0.38 ng/dL
Postmenopausal . . . Up to 0.18 ng/dL

This test was performed using a modified kit approved by the U.S. Food and Drug Administration (FDA). The modification involves one or more of the following: a) media or materials different than those specified in the kit, b) testing was performed on specimen types not specified on the kit insert and/or c) the test procedure has been modified from that provided on the kit insert. The modified test kit has not been cleared or approved by the FDA. The performance characteristics of this test were established through validation by Specialty Laboratories, which is regulated under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") as qualified to perform high complexity clinical testing.

<<< End of text >>>

RUN DATE: 05/11/05
RUN TIME: 1450

Lemuel Shattuck Hospital
Specimen Inquiry

PAGE 1

PATIENT: AUDETTE,LLOYD
REG DR: WARTH,MARIA R MD

ACCT #: LS0001074541 LOC: END.L U #: LS00056059
AGE/SX: 46/M ROOM: REG: 04/05/05
DOB: 12/31/1958 BED: DIS:
STATUS: REG CLI TLOC:

SPEC #: 0405:RB00041R COLL: 04/05/05-1710 STATUS: COMP REQ #: 00115203
RECD: 04/05/05-1716 SUBM DR: WARTH,MARIA R MD

PERFORMING SITE: UMASS MEMORIAL MEDICAL CENTER DIRECTOR: L. MICHAEL SNYDER, MD
ONE BIOTECH PARK
365 PLANTATION STREET
WORCESTER MA 01605-2376 (800)476-4431

ENTERED: 04/05/05-1702 OTHR DR:
ORDERED: FT4, FSH, LH, INTACT PTH, PROLAC, TESTOS FR, TESTOS
COMMENTS: Reason for referral or test? hypogonadism
Primary Diagnosis: 257.2

Test	Result	Flag	Reference
FREE T4	0.70(*d)		0.58-1.64 ng/dL
FSH	13.50(*d)		1.27-19.60 mIU/L
LH	11.10(*d)	H	1.24-8.62 mIU/mL
PTH,INTACT	42(*d)		7-53 pg/mL
PROLAC	8.40(*d)		2.64-13.30 ng/mL
TESTOS FREE	1.18(*d)		0.95-4.30 ng/dL

REFERENCE RANGE for Testosterone Free

Males:
20-49 yrs . . . . . 0.95-4.30 ng/dL
> or = 50 yrs . . . 0.80-3.50 ng/dL
Females:
Ovulating . . . . Up to 0.38 ng/dL
Postmenopausal. . Up to 0.18 ng/dL

This test was performed using a modified kit approved by the U.S. Food and Drug Administration (FDA). The modification involves one or more of the following: a) media or materials different than those specified in the kit, b) testing was performed on specimen types not specified on the kit insert and/or c) the test procedure has been modified from that provided on the kit insert. The modified test kit has not been cleared or approved by the FDA. The performance characteristics of this test were established through validation by Specialty Laboratories, which is regulated under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") as qualified to perform high complexity clinical testing.

TESTOS	652(*d)		262-1593 ng/dL

(*d) UMASS MEMORIAL MEDICAL CENTER LABORATORY
ONE BIOTECH PARK,365 PLANTATION STREET, WORCESTER,MASSACHUSETTS 01605-2376

** END OF REPORT **

UMass Memorial Medical Center
One Biotech Park
365 Plantation Street, Suite 200
Worcester, MA 01605-2376

Laboratory Report

Posted: 04/29/2005 12:22
Printed: 05/11/2005 14:40
Rpt Nbr: 01.1.4476296

Patient Name: AUDETTE,LLOYD BirthDate: 12/31/1958 Sex: M
MRN: YY000308941 Acct: YY000308941

Physician: U - Doctor,Unknown Status: REF
Location: YY-SBCC Admit: 04/25/2005

PV2

Specimen: 20050425:MG00034R Coll: 04/25/2005 00:01

Ordered: HIVBDNA - HIV1 QUANT BY BRANCHED DNA

Test	Result	Flag	Reference
HIVBDNA - HIV1 QUANT BY BRAN	< 75 cop/mL		< 75

VERSANT(R) HIV-1 RNA 3.0 Assay (bDNA) is approved for In Vitro Diagnostic (IVD) use by clinical professionals. This test is intended for use, in conjunction with clinical presentation and other laboratory markers of disease status, as an aid in the management of individuals infected with HIV-1 (Group M, Subtypes A-G). Monitoring the effects of antiretroviral therapy by serial measurements of plasma HIV-1 RNA has been validated for patients with viral loads > 25,000 copies/mL. This test is not intended for use as a screening test for HIV or as a diagnostic test to confirm the presence of HIV-1 infection.

In the absence of previous positive tests demonstrating circulating HIV RNA, values < 500 copies/mL must be interpreted with caution. Additional testing and careful clinical evaluation would be required to determine the significance of such results.

<<< End of text >>>

UMASS MEMORIAL MEDICAL CENTER LABORATORY REPORTS

ONE BIOTECH PARK, 365 PLANTATION ST, SUITE 200 WORCESTER,MA 01605-2376

L. Michael Snyder, MD Director, Laboratories, UMMMC

RUN ON: 04/26/05 1604
RUN FOR: 04/26/05

TYPE OF REPORT: SBCC - Doctor Report
REPORT GENERATED AT UNIVERSITY CAMPUS

PATIENT: **AUDETTE,LLOYD** MR#: PHONE:

LOCATION	AGE	SEX	PHYSICIAN NAME	ACCOUNT #	STATUS	REG DATE
YY-SBCC	46	M	Doctor,Unknown	YY000308941	REG REF	04/25/05
DOB:	12/31/58					

ADM COMMENTS:
SPEC #: 0425:I00217R 16750142 **STATUS:** COMP **COLL:** 04/25/05-UNK **RECD:** 04/25/05-2134

ORDERED: HGB A1C
COMMENTS: W80971

Test	Result	Flag	Reference
> Glycohemoglobin A1C	4.9		4.4-6.0 %

SPEC #: 0425:L00024R 16750142 **STATUS:** COMP **COLL:** 04/25/05-UNK **RECD:** 04/25/05-2134

ORDERED: CD4 LEVELS
COMMENTS: W80971

Test	Result	Flag	Reference
CD4 LEVELS			
> Absolute CD4	[redacted]	L	400-1600 /mm3
> CD4:CD8 Ratio	[redacted]	L	1.20-2.40
> %CD4	[redacted]	L	29-61 %
> %CD8	[redacted]	H	14-32 %
> %CD3	[redacted]	L	56-84 %
> Interpretation			

REDUCED CD4 CELLS.

4/28/05

H = High L = Low * = Panic # = Delta

** END OF REPORT **

EXHIBIT 4

UMASS CORRECTIONAL HEALTH

PROGRESS NOTES

SBCC
Institution

NAME: Audette, Lloyd ID # W580971 D.O.B. 12/31/58

DATE	TIME	IDCM NOTES
1/10/05	1425	Pt called to HSU outPt for Peg injection. Pt voiced No complaints @ this time. Possible SE's reviewed - dosage & Strength reviewed ā Pt. Pt wt today 160# dose is 0.4 mL (96 mcg). Will Flu ā next week. Pt verbalized understanding ~ MJBowen RN.

7113W 1/95

UMASS CORRECTIONAL HEALTH

PROGRESS NOTES

Institution: SBCC

NAME: Audette Lloyd ID # W80971 D.O.B. 12/31/58

DATE	TIME	NOTES
2/3/05	2000	I/m not happy with Lotion says it irratates his hand. Says I Deborah Costa Don't know how to follow up orders. When Lotion was given I/m was informed that there wasn't any Eucerin cream but that Lotion was available. I/m agree to taken the Lotion on 1/31/05. I/M stated that he was allergic to alcohol products and that I should know that. I/m was not Happy with Results [signature]
2/8/05	1430	Follow up: H/O ⊕, Hct, wt ✓ Wt: 149 1/2 # ↓ ō ↓, diarrhea. I/M states eats all his breakfast, grills @ lunch, c̄ dinner. On Resource bid – 500 Kcalories and snacks bid – also 500 Kcal. Should not be ↓ wt. I/M very focused on need for testosterone and study @ MGH. Once again explained he needed to discuss c̄ MD. F/U 3 wks. —— S Bingham [signature] MS RD LDN

UMASS CORRECTIONAL HEALTH

PROGRESS NOTES

SBCC
Institution

NAME: Oudette, Lloyd ID # W80971 D.O.B. 12/31/58

DATE	TIME	NOTES
		IDCM
3/20/05	0930	Spoke c̄ Dr. Hazard RT information regarding Methadone & Antivirals. Reports are showing some HIV medications are both reducing the effects of the HIV medications and/or reducing the effects of the methadone. Above named inmate concerned his chronic pain is due in part from the ↓ effect of the Methadose caused by the Sustiva. Will contact IDMD for advice. ~ M Bowen RN
3/28/05	1350	I/M seen in HSU OPD for HIV clinic. His wt today is 142.5#. I/M is very concerned c̄ wt. loss. Has endocrinologist appt. in Apr. - I/M also concerned c̄ recent article in "the ⊕" which states the effect of methadose is ↓ when combined c̄ Sustiva. Also the article states Methadose ↓'s the effect of DDI. Call (error) Will Call Doc Pharm for recommendations. ~ M Bowen RN
3/28/05	1620	IDCM
		Called placed to Doc Pharm. Left message. Weights since starting HAART. Starting wt 1/10/05 - 160

1/10/05 - 160	1/24 - 153.5	2/7 - 152	2/21 - 149	3/7 - 147	3/21 - 142 3/4
1/17/05 - 153	1/31 - 152.5	2/14 - 153	2/28 - 148	3/14 - 145	3/28 - 142 1/2

~ M Bowen RN

7113W 1/05

UMASS CORRECTIONAL HEALTH

PROGRESS NOTES

SBCC
Institution

NAME: Audette, Lloyd ID # W89971 D.O.B. 10/31/58

DATE	TIME	IDCH NOTES
3/29/05	1135	Doc Pharmacist called & faxed med sheets R/T drug interactions (Sustiva & DDI & Methadose. Page placed to IDMD. ~MJBowen RN
3/29/05	1200	Spoke c Doc Pharmacist (C. Garden) R/T interactions or guidelines for drug interactions - Pharmacist states Using Sustiva could precipitate "withdrawal symptoms for someone using methadose" but NO guidelines where issued - titrating dose could help. Will fax IDMD interaction med sheets — ~MJBowen RN
3/29/05	1330	Faxed med sheets to IDMD ~MJBowen RN
3/29/05	1500	Spoke c Dr Hazard, Dr Tavares, HSA - will speak c Pt on Thursday to discuss possible Dcing of Methadose d/t ↓ efficacy of DDI - also noted was possibility of Symptoms of withdrawal mimic Sts caused by the Rx which could result in toxicity from the methadose being TID. will FU Next week. Pt scheduled to be seen by Endocrinology next week. ~MJBowen RN

7113W 1/95

UMASS CORRECTIONAL HEALTH

PROGRESS NOTES

CD VISIT

SBCC
Institution

NAME: Audette Lloyd ID # W 80971 D.O.B. 12-31-58

DATE	TIME	NOTES
		Problems: 46 yo. w/ ♂ Medications: blood transfusion
3-3-05		Fam. His. - bro AIDS, Hep C 60' fall '80
	3pm	colon cancer 10 mths
		rt finger 45 '78 severed
		Allergies: Codeine Diet:
		baclofen DS ī po QOD
		S: headache "always" 12, 03 liver
		37 TSH .71
		5'6
		O: T: 98.4 P: 86 R: O2 sat: 98 BP: 144/9? Wt: 141 1/2
		HEENT: ⊖ icteric, pale conjunctiva, ⊖ nodes, thyroid
		Cor: RRR no M JVP
		Lungs: clear A/P to auscultation
		Abd: neg tender
		Neuro: A/O x 3 - very flat
		Ext: ⊖ lesion pedal
		Labs: meth ↓ efficacy
		A: coinfected, cotreatment - HIV anti-virals
		wt loss on sustiva sustiva interaction
		discussed low risks
		NSAID, need for cytotoxic monitoring
		P: Chronic Care visit 3 months methadone taper
		RTC if any problems discussed all risks
		~~Inmate education- diet, exercise, compliance~~ with IM.
		See Physician Order Form for Labwork [signature]
		threatened on way out of room LORRAINE HAZARD, M.D.

3 7119W 1/06

UMASS CORRECTIONAL HEALTH
SICK CALL REQUEST FORM

Print Name: Audette Loyd ID#: W80971

Date/Time 4/11/2005 Housing Location: N1

Check **ONLY** One Box: ☒ Medical ☐ Dental ☐ Mental Health

Nature of problem or request: **Medication Non-Compliance Bactrin DS. Refusing**

I consent to be treated by the healthcare staff for the condition described above.

Inmate Signature ____________________

PLACE THIS SLIP IN MEDICAL BOX OR DESIGNATED AREA
DO NOT WRITE BELOW THIS AREA

****

Date/Time Recieved	SBCC Institution	REFERED TO:		
	Frank Rice Slip Sorted by:	☐ Nurse	☒ Midlevel	☐ Physician
		☐ Mental Health	☐ Dental	☐ Other ____

****

Subjective:

Objective: T ______ P ______ R ______ B/P ______ WT ______

Assessment:

Plan [include inmate education]:
This med per ID clinic. continue as ord f/u ID. Dr Stone

Signature & Title: [signature] MARK SCHNABEL, NP Date: ______ Time: ______

8022 Rev. 12/04

UMASS CORRECTIONAL HEALTH

PROGRESS NOTES

SBCC
Institution

NAME: Audette Lloyd ID# W80971 D.O.B. 12-31-58

DATE	TIME	NOTES
		MD F/U Chronic Care
4/12/05		off methadone 20 bid
	3pm	on voltaren vomits ok fsl
		concerned re dwindles
		doesn't want meth back or narcotic
		on sustiva, cytotec, protonix, epivir, didanosine
		flat depressed mood
		can't sleep
		related he knows end approaching
	a	Coinfected
	p	DC voltaren
		Trazodone QHS
		MH referral
		[illegible] trial
		Lorraine Hazard, M.D.
4/18/05	1500	IDCH
		I/M seen today for leg infection - C/o (R) eye issue x ~ 1 week. I/M states (R) eye has a spot in vision - states spot is growing. - Did not give leg will contact [illegible] for direction ~ M Bower RN

7113W 1/95

May 4 8:00

UMass Correctional Health Program

Consultation Request

⊗ Off Site LSH O Emergency [redacted]

O Specialty Clinic Co-infect O Ambulance

[redacted]

Inmate: Audette, Lloyd Inmate ID: W80971 DOB: 12/31/58

Facility: SBCC Cost Center: Incarceration Date:

Estimated Release Date:

Procedure/Test/Specialty Requested: F/U ID (12 wk VL) Provider:

[redacted]

F. 12 wk VL - HCV Rx

Started HCV Rx 1/10/05 c Peg + Ribavirin

Pre Rx VL ??

12/30/04 - 4,609,080 IU/mL + 10 days p starting Rx 1/20/05 - 813,196 IU/mL

[redacted]

12 wk VL drawn 4/7/05 = 13,004 IU/mL

Peg 96 mcg Viread EC

Ribavirin 400 BID 3TC

Sustiva

[redacted]

HIV HCV

[redacted]

Continue c Rx ?

Referring Clinician: Signature: Philip Tavares, M.D. Date: 4/18/05

* For security reasons, inmates must NOT be informed of date, time, or location of proposed treatment or possible hospitalization
* Authorization and payment is provided ONLY for requested procedures or treatments of life-threatening conditions. Prior approval of UMCH State-wide Medical Director is required for additional procedures or hospitalizations

UMASS CORRECTIONAL HEALTH

PROGRESS NOTES

SBCC
Institution

NAME: Audette Lloyd ID # W80971 D.O.B. 12/31/58

DATE	TIME	IDCM NOTES
Late Entry - Entered 4/25/05.		
x 4/20/05 (Call placed from this writers home.)	1030	Call placed to Dr. Barbara McGovern R/T Above inmates issues c eye + recent 50lb wt loss. Dr McGovern (CSH consultation MD) notified of inmates Hx of a "black spot" in center of vision in (R) eye. Pt sent out to CSH on 4/9/05 - has Appt on 4/21/05 c WEMC - will inform her of diagnosis. Also discussed recent ~50lb wt loss. Hx's concern c wasting syndrome - Pt sent out to Endo 4/5/05 Has Flu 5/31 c Endo - will discuss recommended labs c MD/NP - (HbgA1C + Cortisol levels) will book c consultation p lab results are in. ~MJBauer RN

7113W 1/95

EXHIBIT 5

Ht 5'6"

cortisol
lactate
HbA1c
} done / 5/11/15

Lemuel Shattuck

Clinic Visit ~ Follow-up Consultation

Date: 5/11/05 Clinic: Co-inf Primary Provider: McGovern

Vital signs: BP 133/99 P 109 RR 16 Temp 97.6 Wt 147 O2-Sat 100/0

46 YO HIV/HCV coinfected pt c̄ multiple issues:
(1) loss of vision (R) eye + ↓ vision (L) related to detached retina dx at LSH/NEMC.
Had baseline exam at LSH ophtho WNL.
(2) HCV - Pt seen in HIV/HCV Clinic in 2003 c̄ geno 1 infx high viral load. Bx recommended. Seen back in clinic 18 months ago: Bx insufficient + fragmented. Pt s̄ follow-up here since then.
(3) Pt apparently was initiated on PEG Intron + Ribavirin ~ 12 wks ago. At week 12 HCV RNA ↓ by > 2 logs c/w excellent response. However Rx D/C'd 2° to ophthalmologic issues. However relationship unclear.
(4) Pt c/o 50 lb wt loss: CXR recently WNL. Pt seen by endocrinologist + w/u for Testosterone, TFTs etc.
(5) ↓ CD4 count on PEG

☐ Problem List-reviewed/updated

☐ Med. Sheet - reviewed/updated

Page 1 of 2

Consultant's Signature/Print:

Phone/Beeper:

RTC:

White Copy: Medical Records Yellow Copy: Requesting Practitioner

OPO.LS.09/01

Addressograph

Audette, Lloyd

LS0001154236 LS00056059
AUDETTE, LLOYD 12/31/1958
(978)514-6500 COI.L M
UMASS CORRECTI

Lemuel Shattuck

Clinic Visit ~ Follow-up Consultation

Date: 5/11/05 Clinic: Co-inf Primary Provider: McGovern

Vital signs: BP ____ P ____ RR ____ Temp ____ Wt ____ O2-Sat ____

On PE he is thin pale Conj mild injection
O.P. clear Neck No LAD Axilla no LAD
Cor: RRR S1S2 (N) no S3 S4 Lungs clear
Abd: BS nl liver edge 1FB BCM No
Splenomegaly Ext: -c/c/e. Neuro A+O x3

IMPRESSION

(1) HIV: Would ✓ CD4 again in 2 weeks to see if counts ↑ off PEG

(2) HCV: Please order repeat liver bx to stage disease
Had a great response virologically but it is unclear to me if detached retina is related to PEG I am not aware of this association Also sudden onset

(3) Pt has been on Videx > 6 yrs. Will ✓ lactate. Please call Dr Stone to D/C current HIV meds Would consider Truvada + Sustiva instead to avoid mitochondrial toxicity Maybe root of vil loss

☐ Problem List-reviewed/updated

☐ Med. Sheet - reviewed/updated

Page 2 of 2

Consultant's Signature/Print: Barbara McGovern McGovern

Phone/Beeper: ____

RTC: ____

Addressograph

LS0001154236 LS00056059
AUDETTE, LLOYD 12/31/1958
(978)514-6500 COI.L M
UMASS CORRECTI

White Copy: Medical Records Yellow Copy: Requesting Practitioner

OPD.LS.08/01

Lemuel Shattuck

Clinic Visit ~ Follow-up Consultation

Date: 4/5/05 Clinic: Endocr Primary Provider: [illegible]

Vital signs: BP ____ P ____ RR ____ Temp ____ Wt ____ O2-Sat ____

[illegible]

[illegible]

[illegible]

[illegible] Hgb 13.1 WBC 2000 Plt 150 [illegible]

AST 72 ALT 53 TSH 0.71

Imp: ? hypogonadism [illegible]

[illegible] consider pituitary

adenoma as part of MEN I

[illegible] LH FSH, PL, FT4

TSH Cortisol Ca, IPTH all drawn

RTC 3 weeks May [illegible]

☐ Problem List-reviewed/updated

☐ Med. Sheet - reviewed/updated

Page 2 of 2

Consultant's Signature/Print: [illegible] MD

Addressograph

Phone/Beeper: 617-522-8110 X353

RTO: 3 weeks May [illegible]

White Copy: Medical Records Yellow Copy: Requesting Practitioner

OPD.LS.09/01

LS0001074541
AUDETTE, LLOYD
(978) 514-6500
UMASS CORRECTI

LS00056059
12/31/1958
END.L M

UMass Correctional Health Program

Consultation Request

Ø Off Site NEMC O Emergency [redacted]

O Specialty Clinic New England Eye Center O Ambulance

[redacted]

Inmate: Audette, Lloyd Inmate ID: W80971 DOB: 12/31/58

Facility: SBCC Cost Center: _____ Incarceration Date: _____

Estimated Release Date: 11-18-2008

Procedure/Test/Specialty Requested: Retinal Eval Provider: NEMC

c Dr Adam Eagles 617-636-5486

[redacted]

? Retinal detachment - Cause ? Peg Interferon

[redacted]

Seen @ LSH eye Clinic on 4/19/05 - Emergent

Per LSH eye Clinic - See attached

[redacted]

2/8/05 CD4 137 15% 2/8/05 HIV UL 475 4/7/05 Hep C VL 13,800,000 IU/ML

[redacted]

Peg (96mcg) Rib 400 BID Sustiva DDI EC Epivir

HIV. HCV

[redacted]

Started Peg 1/10/05 - 12 wk VL drawn 4/7/05 = 13,800,000 IU/ML

Pre Rx VL was 4.6 million.

Referring Clinician: [signature] Signature: Philip Tavares, M.D. Date: 4/20/05

* For security reasons, inmates must NOT be informed of date, time, or location of proposed treatment or possible hospitalization
* Authorization and payment is provided ONLY for requested procedures or treatments of life-threatening conditions. Prior approval of UMCH State-wide Medical Director is required for additional procedures or hospitalizations

UMass Correctional Health Program

Consultation Request

April 5
2:00

(X) Off Site LSH
( ) Specialty Clinic
( ) Emergency
( ) Ambulance

[redacted]

Inmate: Audette, Lloyd Inmate ID: W80971 DOB: 12/31/38

Facility: SBCC Cost Center: _____ Incarceration Date: _____

Estimated Release Date: _____

Procedure/Test/Specialty Requested: Endocrinology Provider: _____

[redacted]

Need for Testosterone

[redacted]

[redacted]

[redacted]

[redacted]

2.5.04
Free testosterone 1.80

[redacted]

Interferon 96 mcg weekly Sustiva Methadose 20omg BID.
Rebavirin 400 BID Delavirdine
Epivir
Protonix

[redacted]

HIV - Hep C

[redacted]

[redacted]

Per problem list- Zollinger, Ellison Syndrome

States he uses on Testosterone while in streets since stopping continues to loose muscle mass

Referring Clinician: _____ Signature: A. ENAW, M.D. Date: 2/4/05

* For security reasons, inmates must NOT be informed of date, time, or location of proposed treatment or possible hospitalization
* Authorization and payment is provided ONLY for requested procedures or treatments of life-threatening conditions. Prior approval of UMCH State-wide Medical Director is required for additional procedures or hospitalizations

EXHIBIT 6

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BETA
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Contact Us
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HIV Viral Load Supercedes CD4 Count as Best Marker for Predicting Risk of AIDS and Death

by Ronald Baker, PhD

"The extent of viremia, measured by HIV RNA, is the best available surrogate marker of HIV disease progression. Use of HIV RNA as a surrogate marker should help guide future therapeutic research and individual patient management."
--John Mellors and others. Prognosis in HIV-1 infection predicted by the quantity of virus in plasma. Science 272: 1167-1170. May 24, 1996.

Using Chiron Corporation's branched-chain DNA (bDNA) test, John Mellors and colleagues at the University of Pittsburgh conclude that viral load predicts the risk of HIV disease progression (time to AIDS and death) better than CD4 count. The study population consisted of 180 gay and bisexual men enrolled in the Pittsburgh subset of the Multicenter AIDS Cohort Study (MACS). The Pittsburgh researchers' new findings have important implications for the management of HIV disease. Based on these and other study results, viral load testing is expected to supercede CD4 count as the principal marker for guiding individual HIV treatment decisions and for evaluating the effectiveness of anti-HIV drugs in clinical studies.

Armed with accurate measurements of the amount of HIV in their blood plasma as measured by HIV viral load testing, physicians and patients can make more informed decisions about when to start anti-HIV therapy, when to stop using an ineffective treatment and when to add or switch to a new treatment. In addition, monitoring viral load over time allows patients to make treatment decisions much earlier, prior to a significant loss of CD4 cells and well before clinical decline occurs. CD4 cell loss is thought to be a relatively late result of increased HIV replication. Therefore, it appears more beneficial to make anti-HIV treatment decisions based

on HIV viral load rather than on CD4 cell count alone, particularly when the CD4 count is greater than 500 cells/mm^3 (see Research Notes).

When to Start Anti-HIV Therapy?

The article on viral load in *Science* adds a new dimension to the ongoing debate about the optimal time to start anti-HIV treatment. The Pittsburgh cohort data suggest that the appropriate time to initiate therapy is *when HIV viral load exceeds 10,000 copies/mL, regardless of CD4 cell count.* Many individuals in the study with CD4 counts greater than 500 cells/mm^3 progressed as rapidly to AIDS and death as those with much lower counts *when their viral load levels were greater than 10,190 copies/mL.* In current clinical practice, a CD4 cell count of fewer than 500 CD4 cells/mm^3 is commonly used as the trigger to start anti-HIV treatment. This recommendation needs to be reconsidered, given the researchers' finding that 50% of the men in the study with greater than 500 CD4 cells/mm^3 (median CD4 count 781 cells/mm^3) at study entry and a viral load greater than 10,190 copies/mL died within 6 years after entering the study. In comparison, only 5% of those in the same cohort with similar CD4 counts (median CD4 count 787 cells/mm^3) at study entry and viral loads less than 10,190 copies/mL died within 6 years.

The implication of these findings is clear: *the decision to begin anti-HIV therapy should not be based solely on CD4 cell counts. Individuals should consider starting anti-HIV therapy when their viral load is greater than 10,000 copies/mL, regardless of their CD4 cell count.* These conclusions do not diminish the value of CD4 cell testing in the management of HIV disease, which continues to serve as a reliable marker for predicting the risk of opportunistic infections and for determining the appropriate timing of initiating preventive treatment for these infections. In addition, many clinicians believe that a CD4 count less than 350 cells/mm^3 represents an indication for starting anti-HIV therapy, regardless of HIV viral load.

Viral load level (HIV RNA copies/mL): less than 4,531
Median time to AIDS (years): greater than 10
Median survival time (years): greater than 10

Viral load level (HIV RNA copies/mL): 4,531-13,020

Median time to AIDS (years): 7.7
Median survival time (years): 9.5

Viral load level (HIV RNA copies/mL): 13,020-36,270
Median time to AIDS (years): 5.3
Median survival time (years): 7.4

Viral load level (HIV RNA copies/mL): greater than 36,270
Median time to AIDS (years): 3.5
Median survival time (years): 5.1

Viral Load and Disease Progression

The University of Pittsburgh investigators followed study participants for up to 11 years. They determined 4 groups of increasing viral load levels at study entry, and correlated each one with progression to AIDS and survival. The following chart outlines the results of their findings.

In this cohort of men, baseline HIV viral load levels correlate directly with time to AIDS diagnosis and with survival time. Simply stated, the *lower* the viral load, the *longer* the time to AIDS diagnosis and the *longer* the survival time. Conversely, the *higher* the viral load, the *shorter* the time to AIDS and the *shorter* the survival time. The study results indicate that HIV RNA levels can predict disease progression as far as 10 years into the future.

The investigators also noted that when study participants are divided into 2 levels based on their viral load at entry -- greater than 10,190 or less than 10,190 copies/mL -- a surprising trend emerges. The 10-year rate of survival was 70% for those with less than or equal to 10,190 copies/mL compared to a survival rate of only 20% for those with greater than 10,190 copies/mL, including those in this group who had greater than 500 CD4 cells/mm^3 at entry!

New Treatment Recommendations

Researchers at the University of California at San Francisco-affiliated San Francisco General Hospital (SFGH) have formulated interim recommendations on how to interpret viral load test results in conjunction with CD4 cell counts (see Research Notes). A group of researchers and clinicians from the International AIDS

Society-USA also has published recommendations on how to interpret viral load test results (Michael Saag, MD, and others. *Nature Medicine* 2: 625-629. May 1996).

In these recommendations, the critically important numbers are *fewer than 5,000 copies/mL* and *greater than 10,000 copies/mL*. An HIV viral load test result of 5,000 copies/mL or less suggests a low level of viral replication, and probably no immediate need to start therapy, unless the CD4 count is less than 350 cells/mm^3 (**NOTE:** some researchers argue that any level of HIV activity above the level of detection of the test used ought to prompt treatment!) A test result of 10,000-50,000 copies/mL or greater suggests significant viral replication, and the SFGH recommendation is to *consider therapy, regardless of CD4 cell count*. The higher the viral load, the higher the risk for clinical decline and the more pressing the need to begin (or change) treatment. ***A test result of over 100,000 copies/mL may predict a rapid deterioration in clinical status. At this high level of HIV RNA concentration, the recommendation is to immediately start (or change) anti-HIV treatment.***

FDA Approves Roche Viral Load Test for Prognosis

The U.S. Food and Drug Administration (FDA) approved the Amplicor HIV-1 Monitor Test (the viral load test from Roche Molecular Systems Inc.) for HIV disease prognosis on June 3, 1996, seven months after Roche submitted an application for approval. This test is called the reverse transcriptase polymerase chain reaction (RT-PCR) test or simply "PCR." FDA is expected to approve Quantiplex (the viral load test from Chiron Corporation) in the near future. The Chiron test is commonly called the branched-chain DNA test or simply "bDNA." Researchers have found that both the Roche PCR and the Chiron bDNA tests give comparable results in measuring HIV RNA levels in the blood plasma. Both tests cost $150-$200 per test, a price set by the laboratories where the tests are processed. The cost is expected to decline as laboratories face increased competition from each other. Roche has announced plans to offer 2 free HIV RNA baseline tests to all HIV positive patients in the U.S. over a 60-day period starting June 17, 1996. Call 888-TEST-PCR for more information.

Some researchers prefer the Chiron bDNA test because it is simpler to conduct and provides a direct quantification of the HIV RNA in plasma. Others prefer the Roche PCR test because it is more sensitive and capable of measuring HIV RNA levels as low as 400 copies/mL. Both Roche and Chiron have developed more sensitive second generation HIV RNA tests, which are not yet available except in research settings. The second generation bDNA test will measure HIV RNA levels as low as 300 copies/mL; the new Roche test will measure HIV RNA levels as low as 20 copies/mL.

Whichever test is chosen -- the Roche PCR or the Chiron bDNA -- it is important to continue using that same test to determine future HIV RNA values. At present, it is also advisable to use only the Roche or the Chiron test kits rather than "generic" viral load test kits from a laboratory. For now, only the Roche and Chiron tests can be expected to give consistent, reliable and comparable results. A third test that is also accurate and reliable -- the nucleic-acid sequence-based amplification (NASBA) test from Organon Teknika -- is more commonly used in Europe than in the U.S.

In using viral load testing to determine the level of HIV concentration, it is necessary to obtain a baseline value for each patient against which all future values can be compared. This is achieved by averaging the results from 2 viral load tests taken 2-4 weeks apart It is also important to base treatment decisions on *sustained* changes in viral load, not on a single measurement. Certain factors, such as vaccination for influenza and herpes simplex outbreaks transiently increase HIV levels in the bloodstream; other types of immunizations and other acute illnesses also may transiently increase HIV replication. Therefore, patients should avoid taking a viral load test for about 4 weeks following immunizations and after resolution of acute illnesses. When monitoring viral load results over time, it is important to note that only increases or decreases in viral load values of *3-fold or greater* are considered significant enough to warrant a change in treatment regimen. For example, if an individual not on anti-HIV therapy with a baseline viral load test result of 4,000 copies/mL takes the test 3 months later and has a test result of 8,500 copies/mL, the increase is not considered significant because it is less than 3-fold. However, if the new test result is 12,500 copies/mL or higher, the change is significant (greater than 3-fold), and the physician and patient should discuss starting treatment.

Viral Load Results for Evaluating the Success of Therapy

In the coming months, more and more physicians will use the Roche and Chiron viral load tests to monitor the effects of anti-HIV therapy in their patients. Researchers have employed these test for several years in AIDS drug research to help evaluate the effectiveness of AIDS drugs. For example, FDA granted accelerated approval to the protease inhibitor drugs saquinavir, ritonavir and indinavir based in large measure on their ability to significantly decrease viral load as measured by HIV RNA in HIV positive individuals. Within a short time, viral load testing is expected to become an FDA-approved method for demonstrating how well a particular anti-HIV drug or drug combination works, without having to wait for clinical outcomes. In the future, anti-HIV drugs may be routinely evaluated based on whether or not they produce a sustained, significant decrease in viral load. Use of viral load testing also may dramatically shorten the time needed to test drug effectiveness. This could save millions of dollars in research costs by dramatically reducing the need for long clinical studies.

The increasing availability of the 3 new protease inhibitor drugs and of viral load testing has ushered in a new era in the treatment of HIV disease. With increased access to this powerful new technology and to a new class of potent anti-HIV drugs, we are closer to achieving the goal of making HIV disease a chronic manageable illness.

Ronald Baker is Editor-in-Chief of BETA and Director of Treatment Education and Advocacy at the San Francisco AIDS Foundation.

Page last updated 30 July 1996